

EXHIBIT U

Supplemental Declaration of Katherine Zeigler, West Tennessee Regional Administrator of the
Health Facilities Commission of the State of Tennessee

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TENNESSEE
KNOXVILLE DIVISION

STATES OF TENNESSEE, ALABAMA,)
ARKANSAS, GEORGIA, IDAHO, INDIANA,)
IOWA, LOUISIANA, MONTANA,)
NEBRASKA, NORTH DAKOTA, OHIO,)
SOUTH CAROLINA, SOUTH DAKOTA, and)
WEST VIRGINIA,)

Plaintiffs,)
)

v.)
)

U.S. DEPARTMENT OF HEALTH AND)
HUMAN SERVICES; XAVIER BECERRA, in)
his official capacity as Secretary of Health and)
Human Services; and U.S. DEPARTMENT OF)
HEALTH AND HUMAN SERVICES OFFICE)
OF CIVIL RIGHTS,)

Defendants.)

Civil Action No. 25-cv-00025

DECLARATION OF KATHERINE ZEIGLER

Pursuant to 28 U.S.C. § 1746, I, KATHERINE ZEIGLER, duly affirm under penalty of perjury as follows:

1. I am over 18 years of age, have personal knowledge of the matters set forth herein, and am competent to make this declaration.

2. I serve as West Tennessee Regional Administrator of the Health Facilities Commission (“HFC”) of the State of Tennessee. HFC’s mission is to protect patients and promote quality in healthcare facilities throughout Tennessee. To that end, HFC investigates complaints regarding patient safety and facility conditions to ensure compliance with federal, *see* 42 C.F.R. § 482.1, *et seq.*, and state standards, *see* Tenn. Code Ann. §§ 68-11-207, 68-11-210.

3. For example, HFC conducts certification and compliance surveys of health facilities that participate in Medicare to ensure the facility maintains compliance with conditions of program participation. *See* 42 C.F.R. § 489.53(a)(18). These surveys are often undertaken in response to patient complaints regarding care and conditions at healthcare facilities. HFC must have “immediate access” to “provider or supplier” records and facilities “for the purpose of determining” compliance. *Id.* Failure to grant such access could result in the U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services (“CMS”) “terminat[ing]” its agreement with the provider. *Id.* § 489.53(a).

4. In conducting surveys pursuant to state and federal law, HFC regularly requests provider records that contain protected health information under the Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, 110 Stat. 1936 (1996) (“HIPAA”). These requests are most often directed to the facility under investigation, but sometimes it is necessary to request records from other providers along the patient-care chain to adequately investigate certain complaints. For example, if a patient complains that they suffered harm after being transferred to a new facility, it may be necessary to compare the patient records at prior facilities to track the diagnoses and care the patient received.

5. Because of their obligations under state and federal law, *see, e.g.*, Tenn. Code Ann. § 68-11-210 *et. seq.*; 42 C.F.R. § 489.53(a)(18), healthcare facilities are required to provide records in accordance with the survey process.

6. I am aware of the U.S. Department of Health and Human Services’ *HIPAA Privacy Rule to Support Reproductive Health Care Privacy*, 89 Fed. Reg. 32,976 (Apr. 26, 2024) (the “Final Rule”), which took effect on June 25, 2024, although compliance with the Final Rule generally was not required until December 23, 2024, *id.* at 32,976.

7. The Final Rule has required HFC to spend time and resources considering how it can comply with the rule's new attestation requirement. This includes reconsidering our processes and systems for requesting information. This review has involved internal consultation at HFC as well as discussions with the Tennessee Attorney General's office and extended discussions with healthcare facilities and the Tennessee Hospital Association. Given its authorities as the State Survey Agency for Tennessee under its agreement with CMS pursuant to Section 1864 of the Social Security Act, HFC has also sought clarification from CMS and the Association of Health Facility Survey Agencies about complying with the Final Rule, but uncertainty remains. Indeed, CMS has offered inconsistent guidance. Typically, CMS communicates any interpretation or guidance to State Survey Agencies in a Quality Safety and Oversight ("QSO") Memorandum. But no written guidance in the form of a QSO has been provided to date.

8. The Final Rule is currently hindering HFC's investigation of healthcare facilities. For example, HFC recently commenced an investigation into a healthcare facility pursuant to a complaint. As part of that investigation, HFC sought medical records related to the care and treatments of the complainant patient. Specifically, HFC requested emergency medical treatment records from a hospital involving the transport of a patient from a psychiatric hospital who had overdosed on medication. Surveyors were seeking no information regarding the patient's reproductive status, merely the condition upon arrival for emergency treatment. Surveyors were told that they were unable to be provided records, unless an attestation was signed.

9. Further, in several other instances, HFC surveyors have sought admitting diagnoses from hospitals regarding patients who are transported from nursing facilities due to falls, burns, or other injuries which occurred in certified and licensed nursing facilities. In multiple instances,

hospitals have indicated that they are unable or unwilling to release the records without a signed attestation or in some instances a subpoena.

10. Finally, in another instance, a surveyor sought information regarding end stage renal dialysis treatment as part of a recertification and complaint for an end stage renal dialysis facility (a facility which dialyzes patients in end stage renal failure). The hospital refused to give records to the surveyor, citing the Final Rule.

11. Because non-complaint use or disclosure of HIPAA-protected information carries criminal liability, HFC's surveyors have declined to reflexively sign the requested attestations. Instead, surveyors have engaged in a dialogue with the healthcare facility, their legal counsels, and privacy officers, to determine whether the facility could provide the requested information even without an attestation. There have been instances since the Final Rule became effective in which negotiations with a healthcare facility have allowed HFC to obtain *some redacted* records without supplying an attestation. But the records HFC has received in those cases have been incomplete and were delivered only after significant discussions with the healthcare facility to ensure compliance with the Final Rule.

12. While engaging with the healthcare facility about the requested records, the HFC surveyors spend time and resources considering the propriety of the requested attestation. For example, in the case involving a psychiatric hospital, the surveyor considered whether any of the information requested was potentially related to reproductive healthcare. The patient was a seventy-two (72) year old man and the surveyor was simply seeking information about whether or not the patient had an overdose. Still, the surveyor's analysis was made more difficult because the investigation was in an early stage, making it hard to predict what unlawful activity it might encompass or uncover. To date, HFC has not received these records. As a result, the investigation

is still in “pending” status and is unable to be completed. This investigation has now been open for several weeks and is unable to be timely completed.

13. Surveyors’ analyses of attestation requests have been further complicated by the Final Rule’s vague, broad definition of “reproductive health care.” After all, the human body’s organ systems are interrelated, so care may “affect[] the health of an individual in [some] matters *relating to* the reproductive system and to its *functions and processes*” even if it would not be generally considered “reproductive health care.” 89 Fed. Reg. at 32,993. Surveyors therefore have had to engage in internal discussion with colleagues and leadership at HFC about the ends and bases for their investigations. They also have engaged with legal counsel given the Final Rule’s vague definition of “reproductive health care”

14. Under the Privacy Rule, which preexisted the Final Rule, HFC surveyors did not have to take such cumbersome steps to receive necessary information for investigations of health facilities.

Katherine Zeigler, Digitally signed by Katherine Zeigler
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